

CHAPTER 44:03:01
RADIATION CONTROL

Section

- 44:03:01:01 Definitions.
- 44:03:01:02 Licensing of radiation-producing devices and materials, Repealed.
- 44:03:01:03 Transferred.
- 44:03:01:04 Application for license.
- 44:03:01:05 Repealed.
- 44:03:01:06 Annual license renewal.
- 44:03:01:06.01 Exemption from radiation licensing.
- 44:03:01:06.02 Repealed.
- 44:03:01:07 Repealed.
- 44:03:01:07.01 Licensing of radiation producing devices for temporary use.
- 44:03:01:08 Prohibited uses of radiation.
- 44:03:01:08.01 Repealed.
- 44:03:01:08.02 Equipment standards for medical diagnostic X ray ~~machines~~ systems.
- 44:03:01:08.03 Equipment standards for medical fluoroscopic X ray ~~machines~~ systems.
- 44:03:01:08.04 Equipment standards for medical fluoroscopic spot film devices, Repealed.
- 44:03:01:08.05 Periodic measurement of medical fluoroscopic spot film devices, Repealed.
- 44:03:01:08.06 Equipment and operation standards for dental X ray ~~machines~~ system.
- 44:03:01:08.07 Equipment standards for mobile X ray equipment.
- 44:03:01:08.08 Equipment standards for computed tomography systems.
- 44:03:01:08.09 Hand-held intra-oral radiographic imaging device reporting.
- 44:03:01:09 Evaluation and correction of hazards.
- 44:03:01:10 General safety provisions to protect persons from radiation exposures.

- 44:03:01:10.01 Requirements for personal protective devices.
- 44:03:01:10.02 Operator protection requirements.
- 44:03:01:10.03 Reports of incidents involving radiation sources.
- 44:03:01:10.04 Requirements of X ray film processing and darkroom.
- 44:03:01:10.05 Quality assurance program requirements.
- 44:03:01:11 Repealed.
- 44:03:01:11.01 Shielding plan review prior to installation of radiation facilities or equipment.
- 44:03:01:11.02 Installation requirements of all radiation equipment.
- 44:03:01:11.03 Notification of installation of radiation equipment.
- 44:03:01:11.04 Licensee requirements after installation of radiation equipment.
- 44:03:01:11.05 Installation, maintenance, and operation of radiation equipment.
- 44:03:01:12 Repealed.
- 44:03:01:12.01 ~~Radiation~~ X-radiation producing equipment calibration.
- 44:03:01:12.02 Surveys of ~~radiation~~ X-radiation producing facilities and ~~radiation~~ X-radiation producing equipment.
- 44:03:01:13 Transferred.
- 44:03:01:14 Repealed.
- 44:03:01:14.01 Operator requirements for ~~X-ray~~ X-radiation producing equipment.
- 44:03:01:14.02 Operator training requirements for ~~diagnostic radiation~~ X-radiation producing equipment -- Diagnostic computed tomography excluded.
- 44:03:01:14.03 Operator continuing education requirements.
- 44:03:01:14.04 Operator requirements for computed tomography equipment.
- 44:03:01:15 Disposal of radioactive materials.
- 44:03:01:16 Loss or theft of radioactive material.
- 44:03:01:17 Amendment, suspension, or revocation of license.

44:03:01:01. Definitions. Terms defined by in SDCL 34-21-2 have the same meaning when used in this chapter. In addition, ~~the~~ terms used in this chapter mean:

(1) ~~"Added filtration," any filtration that is in addition to the inherent filtration~~ "Air kerma," the kinetic energy released per unit mass of air or the measurement of radiation energy in joules (J) absorbed per kilogram (kg) of air expressed as J/kg or Gray (Gy);

(2) "Aluminum equivalent," the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question;

(3) ~~"Assembler," any person engaged in the business of assembling, replacing, or installing one or more components into an X ray system or subsystem. The term includes the owner of an X ray system or the owner's employee or agent who assembles components into an X ray system that is subsequently used to provide professional or commercial services;~~

~~—(4) "Automatic exposure control (AEC)," a device that automatically controls one or more technique factors in order to obtain at a preselected location a required quantity of radiation. The term includes devices such as,~~ including phototimes and ion chambers;

~~(5)(4) "C-arm X ray system," and X ray system where the image receptor and X ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship and which is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient~~ a mobile fluoroscopy imaging system;

~~(6)(5) "Certified components," components of X ray systems that are subject to regulations by the Food and Drug Administration under the Radiation Control for Health and Safety Act of 1968, Pub. L. No. 90-602~~ Safe Medical Devices Act of 1990, Pub. L. No. 01-629 (November 28, 1990);

~~—— (7) "Certified system," any X ray system that has one or more certified components;~~

(8)(6) "Computed tomography," or "CT," the production of a tomogram by the acquisition and computer processing of X ray transmission data;

(9)(7) "Control panel," ~~that~~ the part of the X ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors;

~~—— (10) "Cooling curve," the graphical relationship between heat units stored and cooling time;~~

~~—— (11) "CRT," cathode ray tube in which cathode rays are used to produce an image on a fluorescent screen;~~

~~—— (12) "Dead man switch," a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator;~~

~~—— (13)(8) "Department," the Department of Health;~~

(9) "Diagnostic source assembly," the tube housing assembly with a beam-limiting device attached;

(14)(10) "Diagnostic X ray system," an X ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization;

~~—— (15) "Diagnostic X ray imaging system," an assemblage of components for the generation, emission, and reception of X ray and the transformation, storage, and visual display of the resultant X ray image;~~

(16)(11) "Dose," a quantity of radiation exposure to the whole ~~anatomy~~ human or animal body or any portion of the human or animal body;

(17)(12) "Exposure survey," an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radiation. ~~When appropriate, such an evaluation includes that~~ may include a physical survey of materials and equipment and measurements of levels of radiation or concentration of radioactive material present;

(18)(13) "Fluoroscopy imaging assembly," a subsystem in which X ray photons produce a

visible image. ~~The term includes simultaneously and continuously including the image receptor such as the, image intensifier, spot film spot imaging device, electrical interlocks, if any, and or structural material providing linkage between the image receptor and diagnostic source assembly;~~

——(19) ~~"Gonad shield," a protective barrier for the testes or ovaries;~~

——(20) ~~Half value layer," the thickness of specified material that attenuates the beam of radiation to an extent such that the exposure rate is reduced by one half. For the purpose of this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded;~~

(21)(14) ~~"Health Healing arts," those professional disciplines authorized by the laws of South Dakota (SDCL chapter 36-2) to use X ray or radioactive material in the diagnosis or treatment of human or animal disease;~~

(22)(15) ~~"Heat unit," a unit of energy equal to the product of the peak kilovoltage, milliamps (mAs), and seconds, i.e. kVp x mA x second;~~

——(16) ~~"High radiation area" an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem, or one mSv in one hour at thirty centimeters from the radiation source or thirty centimeters from any surface that the radiation penetrates;~~

(23)(17) ~~"Image intensifier," a device, installed in its housing, that instantaneously converts an X ray pattern into a corresponding light image of higher intensity;~~

(24)(18) ~~"Image receptor," any device, such as a fluorescent screen or radiographic film, that transforms incident X ray photons either into a visible image or into another form that can be made into a visible image by further transformations;~~

——(25) ~~"Inherent filtration," the filtration of the useful beam provided by the permanently installed components of the tube housing assembly;~~

——(26) ~~"kVp," the maximum value in kilovolts of the potential difference of an X ray generator;~~

~~(27)~~(19) "Lead equivalent," the thickness of lead affording the same attenuation as the material in question;

~~——(28) "Leakage radiation," any radiation coming from within the source housing except for the useful beam and radiation produced when the exposure switch or timer is not activated;~~

~~(29)~~(20) "Licensed practitioner of the healing arts," ~~health professionals~~ a person authorized in accordance with SDCL chapter 36-2 for the diagnostic or healing treatment of human and animal and maladies licensed by the state of in South Dakota ~~(SDCL chapter 36-2)~~ for the lawful practice of medicine;

~~(30)~~(21) "Light field," ~~that~~ the area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection;

~~——(31) "mA," milliamperere;~~

~~——(32) "mAs," milliamperere second;~~

~~(33)~~(22) "Patient," an individual or animal subjected to healing arts examination, diagnosis, or treatment;

~~(34)~~(23) "Peak tube potential," the maximum value of the potential difference across the X ray tube during an exposure;

~~——(35) "Personnel monitoring," the use of film badges, pocket chambers, or other devices worn or carried on individuals for the monitoring of personnel exposures to radiation;~~

~~——(36) "Positive beam limitation," the automatic or semi-automatic adjustment of an X ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment;~~

~~(37)~~(24) "Protective apron," an apron made of radiation absorbing materials used to reduce radiation exposure;

(38)(25) "Protective glove," a glove made of radiation absorbing material used to reduce radiation exposure;

(39)(26) "Qualified expert," an individual who possess the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs including ~~health physicists~~ a qualified physicist;

(40)(27) "Qualified instructor," an individual who ~~possess the knowledge, training, and experience in the field of radiation~~ is certified or registered by the American Registry of Radiologic Technologist or qualified expert to teach fundamentals of radiation safety, equipment operation, film processing, digital radiography, emergency procedures, personnel dosimetry, anatomy and physiology, and radiographic positioning;

(28) "Qualified physicist," an individual who is competent to independently provide clinical professional services in one or more of the subfields of medical physics of diagnostic medical physics, nuclear medical physics, therapeutic medical physics, or medical health physics;

—— (41) ~~"Rad," the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram;~~

(42)(29) "Radiation hazard," a condition under which a person might receive radiation in excess of the maximum permissible dose;

(43)(30) "Rem," the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad;

—— (44) ~~"Scattered radiation," radiation that, during passage through matter, has been deviated in direction;~~

—— (45) ~~"Services," may include calibration of radiation producing machines or instruments, radiation protection surveys, shielding design, radiological health consultations, and personnel dosimetry;~~

(46)(31) "Shielding," a primary and secondary protective barrier used to reduce radiation

exposure to the required degree. ~~For the purpose of this term, a primary protective barrier is the material, excluding filters, placed in the useful beam and a secondary protective barrier is the material that attenuates stray radiation;~~

(32) "Sievert" the International System of Units unit of measure for dose equivalent, equivalent dose and effective dose. The dose equivalent and equivalent dose in sievert (Sv) is equal to the absorbed dose in Gray (Gy) multiplied by the radiation weighting factors;

~~(47)(33) "Source-image receptor distance," or "SID," the distance from the source to the center of the input surface of the image receptor;~~

~~—— (48) "Spot film," a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure;~~

~~—— (49) "Spot film device," a device intended to transport or position, or both, a radiographic image receptor between the X ray source and fluoroscopic image receptor. The term includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph;~~

(50)(34) "Stray radiation," the sum of leakage radiation coming from within the source housing, except for the useful beam and radiation produced when the exposure switch or timer is not activated, and scattered radiation that, during passage through matter, has been deviated in direction;

~~—— (51) "Target," the point at which an X ray is produced;~~

(52)(35) "Technique factors," the following conditions of operation:

(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X ray pulses;

(c) For ~~CT~~ computer tomography (CT) X ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X ray pulse width in

seconds, and the number of X ray pulses per scan, or the product of tube current, X ray pulse width, and the number of X ray pulses in mAs;

(d) For CT X ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time if the scan time and exposure time are equivalent; and

(e) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs;

~~(53)~~(36) "Tube," ~~an X ray tube~~ any electron tube that is designed for the conversion of electrical energy into X ray energy;

~~(37)~~ "Useful beam," radiation that that passes through the patient to the image receptor.

~~(54)~~ "Variable aperture beam limiting device," a beam-limiting device that has capacity for stepless adjustment of the X ray field size at a given SID;

~~(38)~~ "Very high radiation area" an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five hundred rads or five grays in one hour at one meter from a radiation source or one meter from any surface that the radiation penetrates.

~~(55)~~(39) "X ray exposure control," a device, switch, or button, ~~or other similar~~ by which an operator initiates or terminates, or both, the radiation exposure. ~~The term may include such associated equipment as, including~~ timers and back-up timers;

~~(56)~~(40) "X ray equipment," an X ray system, subsystem, or component of the system;

~~(57)~~(41) "X ray field," ~~that the~~ the area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection; and

~~(58)~~(42) "X ray system," an assemblage of components for the controlled production of X rays. The term includes minimally an X ray high-voltage generator, an X ray control, a tube housing

assembly, a beam-limiting device, and the necessary supporting structures. ~~Any additional component, which functions with the system, is considered an integral part of the system; and~~
~~—— (59) "X ray tube," any electron tube which is designed for the conversion of electrical energy into X ray energy.~~

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-2 ~~34-21-11~~, 34-21-18.

44:03:01:02. Licensing of radiation-producing devices and materials. ~~Licensing of radiation sources or materials is required for the production, transport, transfer, receipt, acquisition, possession, use, storage, or disposal of radiation sources or materials used in the healing arts. Licensing shall be accomplished using procedures and forms required by the department~~ Repealed.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 26 SDR 96, effective January 23, 2000.

~~—— **General Authority:** SDCL 34-21-4.1, 34-21-15.~~

~~—— **Law Implemented:** SDCL 34-21-11, 34-21-12, 34-21-18, 34-21-20.~~

44:03:01:04. Application for license. Each person ~~having~~ who has a radiation source, a radiation device, or a radioactive material facility shall apply for licensure with the department within ~~30~~ thirty days after the installation of the equipment or purchase of material. ~~The license shall be obtained~~ person must obtain a license before the equipment is operated. The application for license shall licensure must be completed on forms furnished by the department and shall contain all the information required by the form and accompanying instructions. ~~A~~ using the department's licensing program. An applicant must submit a copy of the applicant's current United States Nuclear

Regulatory Commission license ~~must accompany~~ with the application if applying for a radioactive material license.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL ~~34-21-11~~ 34-21-12, 34-21-18.

44:03:01:06. Annual license renewal. The licensee shall notify the department in writing within ~~30~~ thirty days ~~after~~ of any change ~~which makes~~ in the location or other information on machines, devices, or other radiation sources ~~no longer accurate~~. The license ~~shall~~ must be renewed annually ~~during the month of~~ in January ~~on forms supplied by the department~~ using the department's licensing program.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-18, 34-21-22, 34-21-33.

44:03:01:06.01. Exemption from radiation licensing. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from ~~licensing~~ § 44:03:01:06 if the radiation dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 millirem or 0.005 millisievert per hour at five centimeters from any accessible surface of the equipment. Domestic television receivers and ~~CRTs~~ cathode ray tube monitors and televisions are exempt from the licensing requirement in § 44:03:01:06.

Source: SL 1975, ch 16, § 1; transferred from § 44:03:01:03, 6 SDR 93, effective July 1, 1980; 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-20.

44:03:01:08. Prohibited uses of radiation. ~~No person~~ A licensee may be exposed not expose a person to diagnostic or therapeutic radiation except for healing arts purposes and only if the exposure has been authorized by a licensed practitioner of the healing arts or as permitted by 42 U.S.C. §263b in effect on October 25, 2004, with reports going to the person's health care provider for follow-up. ~~No person~~ A licensee may be exposed not expose a person to the useful beam for non-healing arts training, instruction, or demonstration, ~~or other purposes.~~ The following ~~radiation~~ X-radiation producing equipment may not be used and the following specified procedures may not be performed:

- (1) Fluoroscopic devices for fitting shoes;
- (2) Photofluorographic equipment;
- (3) ~~Dental fluoroscopic imaging assemblies~~ Intraoral fluoroscopy for dental examinations;
- (4) Hand-held radiographic or fluoroscopic imaging devices, except for intra-oral radiographic imaging devices;
- (5) The use of fluoroscopy for positioning a patient for general radiographic imaging, except for radiation therapy simulators;
- (6) The use of fluoroscopy and c-arm ~~fluoroscopes~~ X ray system by a person other than a licensed practitioner of the healing arts unless under the supervision of a licensed practitioner of the healing arts;
- (7) The use of direct exposure X ray film, ~~(without intensifying screens),~~ for routine diagnostic procedures other than intraoral dental radiography, therapeutic portal imaging, and industrial radiography;
- (8) Nonimage intensified fluoroscopic X ray equipment; or

(9) The use of X ray equipment for mammography unless specifically designed by the manufacturer for the imaging of the breast.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 26 SDR 96, effective January 23, 2000; 35 SDR 47, effective September 8, 2008.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, 34-21-23.

44:03:01:08.02. Equipment standards for medical diagnostic X ray ~~machines~~ systems.

~~The standards for any medical~~ A diagnostic X ray system must meet the specifications in 21 C.F.R. §§ 1020.30 and 1020.31, in effect on April 1, 2022. In addition, a diagnostic X ray ~~machine~~ are as follows must meet the following standards:

~~(1) The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.";~~

~~—— (2) If the machine contains a battery powered X ray generator, a visual means shall be provided on the control panel to indicate if the battery is in a state of charge adequate for proper operation;~~

~~—— (3) Any leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source may not exceed 100 milliroentgens in one hour;~~

~~—— (4) The filtration or beam quality is considered adequate if the total filtration in the beam is not less than the following table:~~

Operating Voltage vs. Total Filtration Required	
(Total filtration = inherent plus added)	
Operating Voltage	

(Peak kilovolt) (kVp)	(Millimeters aluminum equivalent)
Below 50	0.5 millimeters
50—70	1.5 millimeters
Above 70	2.5 millimeters

—— (5) ~~A variable, positive beam limitation with rectangular area and a light defining device shall be provided for all fixed X ray machines. The X ray beam dimensions may not exceed the size of film used by greater than two percent of SID on any side. The machine shall include a means to align the center of the X ray field with respect to the center of the image receptor to within two percent of the SID. If a light localizer is used to define the X ray field, it shall provide an average illumination of not less than 160 lux (15.0 foot candles) at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Exempt is any X ray machine that is designed with all parameters fixed, including alignment, source to distance, and technique factors;~~

—— (6) ~~The machine shall include a device to terminate the exposure after a preset time. The accuracy of such a device shall be within five percent of the time set for machines manufactured on or after August 1, 1974, and within ten percent of the time set for machines manufactured before August 1, 1974;~~

—— (7) ~~Any deviation of a measured technique factor from an indicated value of kilovoltage peak (kVp) may not exceed any limit specified for that system by its manufacturer or, in the absence of any manufacturer's specifications, the deviation may not exceed ten percent of the indicated value for kVp;~~

—— (8) ~~The coefficient of variation may not exceed 0.10 when all technique factors are held constant. This requirement is met if, when four exposures are made at identical technique factors,~~

the value of the average exposure (E) is greater than or equal to five times the maximum exposure (E max) minus the minimum exposure (E min), i.e., $E \geq 5(E_{\text{max}} - E_{\text{min}})$;

—— (9) MA/mAs linearity requirements apply if the equipment is being operated on a power supply as specified by the manufacturer for any fixed X ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

—— (a) For equipment having independent selection of X ray tube current (mA), the average ratios (X_1) exposure to the indicated milliamperere-seconds product, in units of coulombs per kilograms per milliamperere second (or milliroentgen per milliamperere-seconds), obtained at any two consecutive tube current settings may not differ by more than ten hundredths times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained by two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection;

—— (b) For equipment having a combined X ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector, the average ratios (X_1) of exposure to the indicated milliamperere-seconds product, in units of coulombs per kilogram per milliamperere second (or mR/mAs), obtained at any two consecutive mAs selector settings may not differ by more than ten hundredths times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained by two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection;

—— (10) If two or more radiographic tubes are controlled by one exposure switch, the tube that has been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be on the X ray control panel and also at or near the tube housing assembly which has been selected;

(11)(2) The tube housing assembly supports shall must be adjusted so that the tube housing assembly remains stable during an exposure unless tube housing movement is a designed function

of the X ray system; and

~~—— (12) Any diagnostic X ray system and its associated components used on humans and certified pursuant to the Federal X Ray Equipment Performance Standard (21 C.F.R. Part 1020) as of January 1, 1998, shall be maintained in compliance with applicable requirements of that standard; and~~

~~—— (13)~~(3) All position locking, holding, and centering devices on the machine ~~shall~~ must function as intended by the manufacturer.

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, 34-21-15.

44:03:01:08.03. Equipment standards for medical fluoroscopic X ray ~~machines~~ systems.

~~Fluoroscopic~~ A fluoroscopic X ray equipment shall be image intensified and the standards are as follows system must meet the specifications in 21 C.F.R. §§ 1020.30 and 1020.31, in effect on April 1, 2022. In addition, a fluoroscopic X ray system must meet the following standards:

(1) ~~The filtration or beam quality is considered adequate if the total in the beam is not less than the table below:~~

Operating Voltage vs. Total Filtration Required	
(Total filtration — inherent plus added)	
Operating Voltage	
(Peak kilovolt) (kVp)	(Millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 — 70	1.5 millimeters
Above 70	2.5 millimeters

~~—— (2) A manually reset, cumulative timing device shall be used which must either indicate elapsed time by an audible signal or turn off the apparatus if the total exposure exceeds a predetermined limit in one or a series of exposures. The device shall have a maximum range of five minutes;~~

~~—— (3) Any exposure to the operator's eyes above the screen and to the operator's waist behind the leaded drapes may not exceed 50 fifty milliroentgens per hour; and~~

~~—— (4) For routine fluoroscopy, the tabletop exposure may not exceed:~~

~~—— (a) Ten roentgens per minute with automatic exposure rate control;~~

~~—— (b) Twenty roentgens per minute with optional high level control provided. A continuous signal audible to the operator shall indicate that the high level control is being employed; or~~

~~—— (c) Five roentgens per minute with fluoroscopic equipment without automatic exposure control;~~

~~—— (5) The fluoroscopic X ray field may not exceed the visible area of the image receptor by more than four percent of the SID; and~~

~~(6)(2) A dead-man switch shall must control the fluoroscopic device. For the purposes of this subdivision, dead-man switch mean a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.~~

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, 34-21-15.

44:03:01:08.04. Equipment standards for medical fluoroscopic spot film devices. ~~Any medical fluoroscopic spot film device shall meet the following requirements:~~

~~—— (1) The device shall provide for the adjustment to the size of the spot film selected that is between the source and the patient. Such an adjustment shall be automatically accomplished except~~

~~when the X ray field size is smaller than the selected portion of the film; and~~

~~—— (2) The center of the X ray field shall be aligned with the center of the selected portion of the film to within two percent of the SID Repealed.~~

Source: 26 SDR 96, effective January 23, 2000.

~~—— **General Authority:** SDCL 34-21-4.1, 34-21-15.~~

~~—— **Law Implemented:** SDCL 34-21-4.1, 34-21-15.~~

44:03:01:08.05. Periodic measurement of medical fluoroscopic spot film devices.

~~Periodic measurement of the entrance radiation exposure rate shall be performed by a qualified expert for both typical and maximum values. Such measurements shall be made triennially or after any maintenance of the system which might affect the radiation exposure rate. Results of these measurements shall be posted where any operator may have ready access to such results while using the fluoroscope. Results of the measurements shall include the roentgen per minute, as well as the technique factors used to determine such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results Repealed.~~

Source: 26 SDR 96, effective January 23, 2000.

~~—— **General Authority:** SDCL 34-21-4.1, 34-21-15.~~

~~—— **Law Implemented:** SDCL 34-21-4.1, 34-21-15.~~

44:03:01:08.06. Equipment standards for dental X ray equipment systems. ~~The standards for All dental X ray equipment are as follows systems must meet the specifications in 21 C.F.R. §§ 1020.30 and 1020.31, in effect on April 1, 2022. In addition, a dental X ray system must meet the following standards:~~

~~(1) The leakage radiation from the diagnostic source assembly measured at a distance of one~~

~~meter in any direction from the source may not exceed 100 milliroentgens in one hour;~~

~~—— (2) The filtration or beam quality is considered adequate if the total in the beam is not less than the table below:~~

Operating Voltage vs. Total Filtration Required	
(Total filtration = inherent plus added)	
Operating Voltage	(Millimeters aluminum equivalent)
Below 70	1.5 millimeters
Above 70	2.5 millimeters

~~—— (3) Collimation of the beam shall be restricted to a maximum of three inches in diameter and may not have a pointed cone;~~

~~—— (4) Time accuracy shall be within five percent of the time set for any X ray equipment installed on or after August 1, 1974, and ten percent of time set for any equipment installed before August 1, 1974;~~

~~—— (5) Any deviation of a measured technique factor from an indicated value for kilovoltage peak (kVp) may not exceed any limit specified for that system by its manufacturer or, in the absence of any manufacturer's specifications, the deviation may not exceed ten percent of the indicated value for kVp;~~

(6)(2) The exposure switch ~~shall~~ must be located so the operator can stand at least six feet from the useful beam. If sufficient shielding is provided to protect the operator from stray radiation, the exposure switch may be located closer;

~~—— (7) The target to skin distance shall be at least seven inches;~~

(8)(3) Any dental X ray equipment must operate with a kilovoltage of ~~60~~ sixty kVp or higher;

(9)(4) Any dental X ray machine must be maintained within manufacturer's specifications and recommendations;

(5) Any hand-held intraoral X ray equipment must be equipped with a backscatter shield of not less than 0.25 millimeter lead equivalent and 15.2 centimeters in diameter, positioned as close as practicable to the distal end of the position indication device; and

(6) Any hand-held device must be secured from unauthorized removal or use.

When operating a hand-held intraoral dental radiographic unit, operators shall wear a 0.25 millimeter lead equivalent apron, unless otherwise authorized by the department or a qualified physicist.

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, 34-21-15.

44:03:01:08.07. Equipment standards for mobile X ray equipment. ~~Mobile X ray equipment shall meet the standards of~~ In addition to § 44:03:01:08.02 and as follows:

~~—(1) The mobile X ray equipment must have the exposure switch shall be located so the operator can stand at least six feet from the useful beam. If sufficient shielding is provided to protect the operator from stray radiation, in which case the exposure switch may be located closer; and~~

~~—(2) Any mobile medical radiographic equipment shall have a spacer to limit the target to skin distance to at least 12 inches.~~

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, 34-21-15.

44:03:01:08.08. Equipment standards for computed tomography systems. ~~The standards~~

~~for A computed tomography systems are as follows (CT) system must meet the specifications in 21 C.F.R. §§ 1020.30 and 1020.33, in effect on April 1, 2022. In addition, a CT system must meet the following standards:~~

~~(1) A visible signal must indicate when the X ray exposure has been terminated. The operator must be able to terminate the X ray exposure at any time during a scan or series of scans under CT X ray system control of greater than one half second duration;~~

~~—— (2) For any single slice tomogram system, a means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane. For any multiple slice tomogram system, a means must be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes. If a device using a light source is used to satisfy this subdivision, the light source must provide illumination levels of not less than 160 lux (15.0 foot candles) above the room ambient illumination level;~~

~~—— (3) The X ray control and gantry must visually indicate whenever X rays are produced and, if applicable, whether the shutter is open or closed. Any emergency button or switch must be clearly labeled as to its function. A means shall be provided to require operator initiation of each individual scan or series of scans;~~

~~—— (4) The CT X ray system shall be designed to indicate the CT conditions of operation to be used during a scan or a scan sequence prior to the initiation of a scan or a scan sequence. On equipment having any of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible;~~

~~—— (5) The system shall perform in such a manner that the radiation produced adjacent to the tube housing assembly, including the tube port, during periods of time scans are not being performed does not exceed 100 milliroentgen in one hour;~~

~~—— (6) For CT X ray systems containing a gantry manufactured after September 3, 1985:~~

~~—— (a) The total error in the indicated location of the tomographic plane or reference plane may not exceed five millimeters;~~

~~—— (b) If the X ray production period is less than one half second, the indication of X ray production shall be actuated for at least one half second. Any indicator at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible; and~~

~~—— (c) The deviation of indicated scan increment versus actual increment may not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms, inclusive, resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increments may be taken anywhere along this line travel;~~

~~—— (7) The system must provide for two-way, oral communication between the patient and the operator at the control panel;~~

~~(8)(2) Leaded windows, mirrors, a closed-circuit television, or an equivalent shall must be provided located to permit continuous observation of the operator to continuously observe the patient during irradiation and shall be so located that the operator can observe the patient from the control panel; and~~

~~(9)(3) If the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall must be available for use in the event of failure of if the primary viewing system fails.~~

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, ~~34-21-15~~.

44:03:01:10. General safety provisions to protect persons from radiation exposures. The licensee shall be responsible for directing the operation of any X ray system under the licensee's administrative control. The licensee or the licensee's agent shall ~~provide that~~ ensure:

(1) No X ray system ~~may be~~ is operated for diagnostic purpose unless the system meets the provisions of this chapter;

(2) Any ~~person who is~~ personnel operating the licensee's X ray system is adequately instructed in the safe operating procedures ~~and, is~~ is competent in the safe use of the equipment commensurate with the size, scope, and nature of the service. ~~Any such person shall be instructed, and can~~ demonstrate competence in subjects outlined in § ~~44:03:01:14.01~~ 44:03:01:14.02;

(3) Procedures and auxiliary equipment ~~designed to minimize patient and personnel exposure commensurate with the needed diagnostic information is utilized. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality~~ with minimum patient radiation exposure;

(4) Digital imaging equipment utilized is consistent with the diagnostic objective of the examination;

(5) The film screen combinations are the fastest speed consistent with the diagnostic objective of the examination;

(6) A technique chart or manual is located in the vicinity of the control panel of each machine that specifies, for all diagnostic examinations performed with that system, the following information:

(a) The technique factors to be used that are specific to a patient's anatomical part, size, or, if pediatrics, age ~~(for pediatrics)~~, except for any system that has only automatic X ray exposure controls;

(b) The type of film-screen combination to be used;

- (c) The type of grid to be used, if any;
- (d) The source-image receptor distance (SID) to be used, except for dental and all other fixed SID radiographic equipment;
- (e) The type and placement of patient shielding to be used;
- (f) The routine views for all procedures done with each machine; and
- (g) For mammography, an indication of kVp/target/filter combination. For the purpose of this subsection, target means the point at which an X ray is produced;

~~(5)(7)~~ A written operating and safety procedure ~~must be~~ that includes restrictions for the safe operation of each radiation machine, is available to each individual who operates radiation machines. ~~These procedures shall include restrictions for the safe operation of each radiation machine. The operator shall be~~ and that each operator is able to demonstrate familiarity with these procedures;

~~(6)(8)~~ Except for veterinary facilities licensees, ~~each facility maintains~~ a record containing the patient's name, the type of examination, the date the examination was performed, and equipment operator is maintained;

~~(7)(9)~~ Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure ~~shall be~~ are in the room during the radiographic exposure;

~~(8)~~ ~~Personnel monitoring of radiation exposures and records must be maintained by the licensee of the radiation source. Monitoring with dosimetry devices shall be required for all persons routinely exposed to radiation in their occupation. Dental and podiatry offices are exempt from this requirement. Exposures should not exceed 300 millirems per calendar quarter. Maximum occupation exposures shall not exceed the limits specified in the following table:~~

~~Rems per Calendar Quarter~~

Whole body; head and trunk; active	
blood-forming organs; lenses of eyes; gonads	3 3/4

Hands and forearms; feet and ankles	18 3/4
Skin of whole body	7 1/2

(10) The following licensee's personnel are supplied with appropriate individual monitoring devices and that required personnel are wearing the monitoring devices:

(a) Adults likely to receive in one year, a dose in excess of ten percent of the limits in subdivision (15) of this section;

(b) Declared pregnant women likely to receive, during the entire pregnancy, a dose in excess of 0.1 rem or one millisievert (mSv);

(c) Each individual who enters a high radiation area or very high radiation area; and

(d) Minors likely to receive in one year a dose in excess of 0.1 rem or one mSv;

(11) Each individual monitoring device is assigned to and worn by only one individual;

(12) Personnel who are required to be monitored for occupational doses according to this section wear individual monitoring devices as follows:

(a) An individual monitoring device used for monitoring the dose to the whole body must be worn on the trunk of the body or at the unshielded location of the body likely to receive the highest exposure;

(b) When a protective apron is worn, the individual monitoring device must be worn on the collar outside of the protective apron;

(c) When more than one individual monitoring device is used, the record must identify the location of the monitor on the body and must state whether it was worn outside or under the protective clothing. The effective dose equivalent must be recorded in the reports required by this section; and

(d) When a woman declares her pregnancy to the licensee in writing, a dosimeter must be worn at the level of the abdomen and under any lead shielding;

(13) A control device accompanies a licensee's individual personal monitoring devices during shipment and that the device is kept in an area of natural background radiation at the facility between shipments;

(14) Maintenance of clear and legible personnel dosimetry records showing the radiation doses of all individuals for whom individual monitoring is required according to this section;

(15) Control of the occupational dose to individual adults, except for planned special exposures, to the most limiting of the following annual dose limit:

(a) The total effective dose equivalent being equal to five rem or 0.05 sievert (Sv);

(b) The sum of the deep dose equivalent, defined as the dose to organs or tissues that will receive an intake of radioactive material, and the committed dose equivalent, defined as the whole body dose from an external source of ionizing radiation, to any individual organ or tissue, other than the lens of the eye, being equal to fifty rem or 0.5 Sv; or

(c) The annual limit to the lens of the eye is a lens dose equivalent of fifteen rem or 0.15 Sv; and

(d) The annual limit to the skin and the extremities is a shallow dose equivalent of fifty rem or 0.5 Sv;

(16) When a woman declares her pregnancy in writing, that the dose equivalent to the woman's embryo or fetus does not exceed, during the entire pregnancy, 0.5 rem or five mSv due to occupational exposure;

(17) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, are subtracted from the limits for planned special exposures that the individual may receive during the current year;

(18) The assigned deep dose equivalent and shallow dose equivalent is for the portion of the body receiving the highest exposure;

(19) The deep dose equivalent, lens dose equivalent, and shallow dose equivalent are assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits if the individual monitoring device is not in the region of highest potential exposure or the results of individual monitoring are unavailable;

(20) When a protective apron is worn while working with fluoroscopic equipment and monitoring is conducted as specified in subdivision (10) of this section, the effective dose equivalent for external radiation is determined as follows:

(a) When only one individual monitoring device is used, and it is located at the neck or collar outside the protective apron, the reported deep dose equivalent is the effective dose equivalent for external radiation;

(b) When only one individual monitoring device is used, and it is located at the neck or collar outside the protective apron, the reported deep dose equivalent value multiplied by 0.3 is the effective dose equivalent for external radiation; or

(c) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the collar, the effective dose equivalent for external radiation is assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the collar outside the protective apron multiplied by 0.04; and

(9)(21) Radiation sources shall be labeled and caution signs posted to provide a warning to all persons within the exposure area.

Any alternative method of determining equivalent dose in subdivisions (18), (19), or (20) of this section must be approved by the department.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 26 SDR 96, effective January 23, 2000; 31 SDR 62, effective November 7, 2004.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, 34-21-25, 34-21-26.

44:03:01:10.01. Requirements for personal protective devices. Special personal protective devices ~~shall~~ must be used to protect eyes, skin, bone, and certain active blood-forming organs from unnecessary radiation exposure when possible ~~These protective.~~ The licensee must ensure devices ~~must be~~ are readily accessible and in good working condition.

A gonad shield of not less than 0.5 millimeters lead equivalent material must be used for human patients who have not passed the reproductive age during radiographic procedure in which the gonads are in the useful beam, unless the shield would interfere with the diagnostic procedure or during abdominal or pelvic imaging in which automatic exposure control is used. For the purposes of this section, reproductive age means a person who is at least twelve years old but under the age of fifty-five and is capable of bearing or fathering children.

~~Protective~~ The licensee shall check equipment ~~including aprons, gloves, and shields shall be checked~~ used to reduce radiation exposure annually for defects, ~~such as holes, cracks, and tears to assure reliability and integrity.~~ A The licensee shall make and maintain a record of this test shall be made and maintained. If ~~such~~ a defect is found, the equipment ~~shall~~ must be replaced or removed from service until repaired;

Mechanical-holding devices ~~shall~~ must be used when the technique permits. The individual holder ~~shall~~ must be protected and no individual may be used routinely to hold ~~film~~ the image receptor or ~~patients~~ patient. Written safety procedures ~~shall~~ must indicate the requirements for selecting an individual to be a holder and the procedure the holder shall follow.

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, ~~34-21-15~~, 34-21-25.

44:03:01:10.02. Operator protection requirements. Operators of fixed medical radiographic units shall be within a shielded area large enough to provide protection from unattenuated direct scatter or stray radiation originating from the table or ~~upright cassette holder~~ wall-mounted image receptor. The booth walls must be permanently fixed barriers of at least two meters high.

Operators of dental radiographic units must comply with § 44:03:01:08.06.

A lead glass patient-viewing window, mirrors, closed circuit television, or an equivalent system must be available to permit the operator to continuously observe the patient during exposure. If a patient-viewing window is used, it must be a minimum of one square foot and must be located at least eighteen inches from the edge of the control booth for any new construction and any renovation, addition or change in space use of existing facilities. The exposure switch must be permanently mounted so that it cannot be conveniently operated outside the shielded area.

For mobile and portable X ray systems to be used less than one week in the same location, the control must be positioned so that the operator is at least six feet away from the tube housing and the patient during an exposure and is not exposed to greater than two millirems or 0.02 millisievert in any one hour.

For mobile and portable X ray systems to be used more than one week in the same location, the operator must be provided with a movable protective barrier at least 6.5 feet high, ~~30~~ thirty inches wide, and equipped with a lead glass viewing window.

Source: 26 SDR 96, effective January 23, 2000; 32 SDR 128, effective January 30, 2006.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, ~~34-21-15~~.

44:03:01:10.05. Quality assurance program requirements. The licensee shall have a

written, ~~on-going~~ ongoing quality assurance program specific to the equipment and procedures that are performed in the facility to ensure consistent high-quality images with minimum patient exposure. The tests performed for quality control purposes ~~shall~~ must be included in a log containing acceptability limits, results of tests, date, initials of the operator or testing individual, and corrective action taken, if needed. Tests for film processing ~~shall~~ must include temperature, chemical replacement, processor operating parameters, and darkroom fog, and be performed on a routine basis. Any quality control test done on diagnostic tubes ~~shall~~ must be done annually and include source-image receptor distance (SID) accuracy, X ray and light field alignment, X ray and bucky alignment, and collimator dial accuracy. All dental intraoral, panoramic, tomography, and machines that have fixed SID and collimator are excluded from SID accuracy, X ray and light field alignment, X ray and bucky alignment, and collimator dial accuracy.

A qualified expert shall measure the reference air kerma rate on medical fluoroscopic equipment for typical and maximum values. The measurements must be made annually and after any maintenance of the system that might affect the radiation exposure rate. The results must be posted where any operator may have ready access to them while using the fluoroscopic equipment, unless the equipment has a real-time display of air karm. Results of the measurements must include:

- (1) The roentgen per minute or milliGray per minute;
- (2) The technique factors used to determine the results;
- (3) The name of qualified expert performing the measurements; and
- (4) The date the measurements were performed.

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, ~~34-21-15~~.

44:03:01:11.01. Shielding plan review prior to installation of radiation facilities or

equipment. Prior to construction, the facility owner or the facility's shielding plan designer must submit the floor plans, shielding specifications, and equipment arrangement of any new X-radiation producing equipment installation or any modification of existing X-radiation producing equipment installations ~~utilizing ionizing radiation machines shall be submitted~~ to the department for review and approval. The plans ~~shall~~ must show ~~at a minimum~~ the following:

(1) The normal location of the ~~system's~~ machine's radiation port, the general direction of the useful beam, the location of any windows and doors or other openings, the location of the operator's booth, and the location of the control panel;

(2) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room concerned;

(3) The dimensions of any room concerned;

(4) The type of occupancy of any adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the plans must show distance to the closest area where it is likely that individuals may be present;

(5) The make and model of the equipment, the maximum technique factors, and the energy waveform ~~(single phase, three phase, etc.)~~; and

(6) The type of examinations or treatments ~~which will~~ to be performed with the equipment and the anticipated workload of the system in ~~mA-minutes~~ milliamperes-minutes per week.

The department may require the applicant to utilize the services of a ~~health~~ qualified physicist to determine the shielding requirements prior to the plan review and approval. The approval of ~~such the plans by the department does not~~ may not preclude the requirement for additional modifications should a subsequent change of operating conditions create the possibility of an individual receiving a dose in excess of the limits.

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, 34-21-17.

44:03:01:11.03. Notification of installation of radiation equipment. Any assembler who installs radiation machines in this state shall report to the department within ~~15~~ fifteen days the following information:

- (1) The name and address of the persons who have received these machines;
- (2) The manufacturer, model, and serial number of each radiation machine and major components transferred;
- (3) The date of transfer of each radiation machine; and
- (4) The date of installation of each radiation machine.

In the case of diagnostic X ray systems which contain certified components, the licensee must submit a copy of the assembler's report, Form FDA 2579 (6/95), prepared in compliance with requirements of the Federal Diagnostic X Ray Standard, 21 C.F.R. 1030.30(d), as of ~~January 1, 1998~~ April 1, 2022, ~~shall be submitted~~ to the department within ~~15~~ fifteen days following completion of the assembly.

For the purposes of this section, assembler means any person, including the owner of the X ray system or the owner's employee or agency, engaged in the business of assembling, replacing, or installing one or more components into an X ray system or subsystem that is subsequently used to provide professional or commercial services.

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-15.

Law Implemented: SDCL 34-21-4.1, 34-21-17.

44:03:01:11.04. Licensee requirements after installation of radiation equipment. After completion of construction and installation of radiation equipment, the licensee shall maintain for

inspection:

(1) Model and serial number of all major components and user's manuals for those components;

(2) Records of surveys, calibrations, maintenance, and modifications performed on the X ray systems;

(3) The maximum rated technique factors of each machine with tube rating and cooling curves charts; and

(4) Scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas; the results of a survey for radiation levels present at the operator's position and at pertinent points outside the room; and the type and thickness of materials, or lead equivalency, in each protective barrier used in the room.

For the purpose of this section, cooling curve is the geographical relationship between heat units stored and cooling time.

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-1-17, 34-21-15.

Law Implemented: SDCL 34-21-4.1, 34-21-17.

44:03:01:12.01. ~~Radiation~~ X-radiation producing equipment calibration. The licensee shall ~~provide~~ ensure that calibrations are performed on a diagnostic radiographic system if that system does not meet the minimum performance criteria specified in §§ 44:03:01:08.02 to 44:03:01:08.07, inclusive, and if there is any change or replacement of components that could cause a change in the radiation output of that system.

The calibration ~~may not exceed~~ must be performed within three months after any change or replacement of components that could cause a change in the radiation output. The calibration of the

radiation output of the X ray system ~~shall~~ must be performed by or under the direction of a qualified expert. ~~Calibration of the radiation output of an X ray system shall be performed~~ with a calibrated dosimetry system test meter. Any X ray machine ~~shall~~ must be ~~calibrated at least~~ surveyed by the department or a qualified expert every three years ~~unless it~~ to verify the X ray machine meets the standards of this chapter. Any X ray machine that does not meet the standards of this chapter must be calibrated within three month Any computed tomography system ~~shall~~ must be ~~calibrated or~~ surveyed by a ~~medical~~ qualified physicist within thirty days after clinical use and on an annual basis.

Source: 26 SDR 96, effective January 23, 2000; 32 SDR 128, effective January 30, 2006.

General Authority: SDCL 34-1-17, 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, ~~34-21-15~~.

44:03:01:12.02. Surveys of ~~radiation~~ X-radiation producing facilities and ~~radiation~~ X-radiation equipment. Any new ~~radiation~~ X-radiation producing facility and any existing ~~radiation~~ X-radiation producing facility shall have a radiation exposure survey ~~made~~ by a qualified expert or the department. The survey ~~shall~~ must be ~~done~~ performed after any change in the facility location or equipment repair that might cause a significant increase in radiation hazard. The licensee shall obtain a written report of the survey from ~~a~~ the qualified expert. ~~The licensee shall~~ and transmit a copy of the report to the department within ~~30~~ thirty days of receipt of the report. The survey and department report ~~shall~~ must indicate all instances where the equipment installation, in the opinion of the qualified expert or department, is in violation of ~~the regulations~~ this chapter.

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-15.

Law Implemented: SDCL 34-21-4.1, 34-21-15.

44:03:01:14.01. Operator requirements for ~~X-ray~~ X-radiation producing equipment.

Any person who is certified or registered by the American Registry of Radiologic Technologists (ARRT), licensed in radiologic technology by another state, or who has documented ~~40~~ eighty hours of orientation and training in the operation of ~~radiation~~ X-radiation producing equipment by a qualified instructor, may operate ~~any radiation~~ X-radiation producing ~~device~~ equipment, excluding diagnostic computed tomography equipment. The qualified instructor must verify competency for each procedure the operator will be performing. If a patient is not available, the procedure may be simulated.

____ For the purposes of complying with the provisions of electronic health records certification criteria established pursuant to ~~45 CFR 495.6~~ 42 C.F.R. § 495.60, in effect on September 4, 2014, a radiologic technologist certified ~~and or~~ registered by the ~~American Registry of Radiologic Technologists~~ ARRT or licensed by another state is considered to be a licensed health care professional. Dental radiographers registered in accordance with SDCL chapter 36-6A shall have a minimum of ~~16~~ sixteen hours of training. Chiropractic radiographers licensed pursuant to SDCL chapter 36-5 shall have a minimum of thirty-six hours of training.

Source: 26 SDR 96, effective January 23, 2000; 31 SDR 62, effective November 7, 2004; 42 SDR 51, effective October 13, 2015.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, ~~34-21-15~~.

____ **Reference:** ~~45 CFR 495.6~~, Federal Register, National Archives and Records Administration. Copies may be obtained free of charge at <https://www.federalregister.gov/select-citation/2014/05/23/42-CFR-495.6>.

44:03:01:14.02. Operator training requirements for ~~diagnostic radiation~~ X-radiation producing equipment -- Diagnostic computed tomography excluded. A qualified instructor ~~must~~ shall do all training for operators of ~~diagnostic radiation~~ X-radiation producing equipment.

~~Documentation~~ The instructor or training program must provide a letter or certificate of the training must include the dates, instructor, and subjects covered. The operator shall maintain a record of the training. Continuing education credits ~~would~~ qualify as part of the training. ~~The following are areas in which an individual~~ A licensee must ~~have~~ ensure documented training for the operation of ~~X-ray~~ X-radiation producing equipment in:

(1) Fundamentals of radiation safety ~~must cover,~~ covering characteristics of radiation, units of radiation measurement, hazards of exposure to radiation, levels of radiation from sources, and methods of controlling radiation dose;

(2) Familiarization with equipment ~~must cover,~~ covering identification of controls, function of each control, how each control affects technique chart, and utilization of technique chart;

(3) Film processing ~~must cover,~~ covering film speed as related to patient exposure, film processing with automatic processors, manual film processing ~~manually~~, and factors affecting film processing quality;

(4) Computed radiography or digital radiography image acquisition, covering exposure index values, defined as the numerical value related to the signal to noise ratio squared of the image;

~~(5)~~ (5) Anatomy and positioning relative to scope of practice, including patient preparation, and correct method for performing procedures; and

~~(5)(6)~~ ~~The requirement of federal~~ Federal and state regulations pertinent to the services offered.

Source: 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, ~~34-21-14~~.

44:03:01:14.03. Operator continuing education requirements. ~~Any~~ An operator of ~~a radiation~~ X-radiation producing ~~device~~ equipment shall ~~have five complete eight~~ hours of

documented continuing education over a ~~three-year~~ two-year period ~~containing information on;~~

_____ (1) Radiation safety, ~~equipment~~;

_____ (2) Equipment operation;

_____ (3) Image and film processing, ~~emergency~~ and archiving;

_____ (4) Emergency procedures, ~~anatomy~~, ~~positioning~~;

_____ (5) Anatomy;

_____ (6) Positioning of film and body parts, ~~orientation~~;

_____ (7) Orientation or training in new developed procedures, ~~infection~~;

_____ (8) Infection control; or ~~rules~~

_____ (9) Rules pertinent to the services offered.

_____ Continuing education must be related to imaging competencies performed by the operator.

~~Excluded~~ Practitioners of the healing arts and any employee of a dental or chiropractic facility are excluded from the five hours of continuing education are any licensed practitioner of the healing arts and any employee of a dental facility requirements in this section.

Source: 26 SDR 96, effective January 23, 2000; 31 SDR 62, effective November 7, 2004.

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1, ~~34-21-14~~.

44:03:01:14.04. Operator requirements for computed tomography equipment.

Diagnostic computed tomography (CT) equipment may only be operated by personnel who are certified and registered by the American Registry of Radiologic Technologists or certified and registered in CT by the Nuclear Medicine Technologist Certification Board. This section does not apply to personnel using CT equipment for attenuation correction, radiation therapy planning, or cone beam computed tomography.

Source:

General Authority: SDCL 34-21-4.1, 34-21-15.

Law Implemented: SDCL 34-21-4.1.